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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/06/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/615,285

Applicant(s)

AFAR ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,10-13,15,17-19 and 48-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,10,12,13,15,17,18 and 48-61 is/are rejected.
- 7) ☒ Claim(s) 11 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Response to Amendment***

The Amendment filed June 12, 2002 (Paper No. 15) in response to the Office Action of February 26, 2002 is acknowledged and has been entered.

Claims 4, 8-9, 14, 16, 20-28, and 39-47 were cancelled.

Claims 48-61 were added.

Claims 1-3, 5-7, 10-13, 15, 17-19, and 48-61 are pending.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

***Information Disclosure Statement***

Reference item No. 6 of the IDS filed 12-09-02 (Paper No. 17) was not considered because it was not found in the parent application. An online search was attempted but the reference could not be found because no author name was included in the IDS.

**Rejections/Objections Maintained:**

The specification remains objected to on pages 39-40, for missing ATCC information. Applicants argue (Paper No. 15, pages 9-10) that the hybridomas are being deposited with the ATCC and request that the Office hold this requirement in abeyance until allowable subject matter in this application is indicated. This argument has been considered but is not found

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persuasive. The issues relating to any allowable subject matter are independent from formal matters necessary for a complete and proper specification. Accordingly, any failure to supply the necessary deposit information in response to this Action will be considered non-responsive.

Claims 11 and 19 remain objected to as being dependent upon a rejected base claim, but would be **allowable** if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-3, 5, 7, 10, 12-13, 15, 17-18 remain rejected **and new Claims** 48-51, 53-54, and 56-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong *et al.* (US Patent No. 6,166,194, June 29, 1998).

Applicants argue (Paper No. 15, pages 11-12) that there is absolutely no evidence in Wong that the production of the designated protein in a tissue is characteristic of tumor cell growth or neoplasia. Applicants argue that Wong teaches that it is the “lack of expression of the relevant gene that would be associated with cancer”.

This argument has been considered but is not found persuasive. How Wong describes the biological activity of the TMPRSS2 protein is irrelevant since the sequence of Wong’s protein is the exact same protein as applicants. Moreover, the method steps described in the prior art comprise the same steps as claimed in the instant invention, that is, the prior art teaches a method of examining a biological sample for evidence of tumor cell growth comprising comparing the expression level of the TMPRSS2 gene, which encodes the protein of SEQ ID NO:2, in the biological sample to the expression of the same gene in a corresponding normal sample. And,

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since the product of the prior art is identical to that required by the claims, the method will inherently lead to the determination that levels of TMPRSS2 expression are enhanced in tumor samples compared to corresponding normal samples. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Thus, since the product of the prior art has the same chemical structure as that described in the specification, it can be assumed that the product will inherently perform the claimed process. (See MPEP 2112.02).

Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

#### **New Rejections:**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claims to a protein encoded by a cDNA clone 20P1F12-GTC1 contained in the plasmid deposited with the ATCC as Accession No. 207097 (and in the specification on page 86, line 16) is an insufficient assurance that all of the conditions of 37 CFR sections 1.801

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through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.  
Examiner  
Art Unit 1642

GBN  
April 22, 2003

  
ANTHONY C. CAPUTA  
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